U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Decommissioning Funding Plan (DFP) Requirements for the Medical Use of Germanium-68/Gallium-68 Generators

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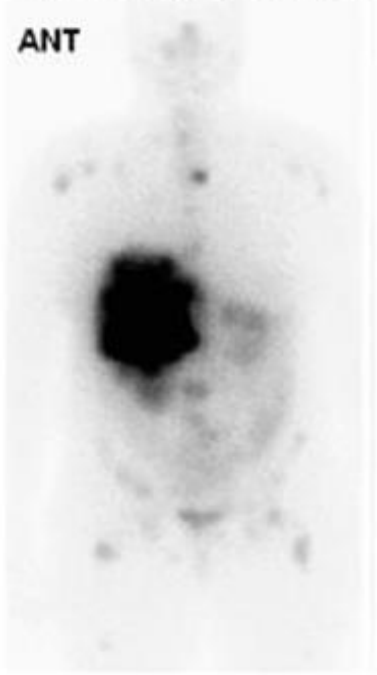
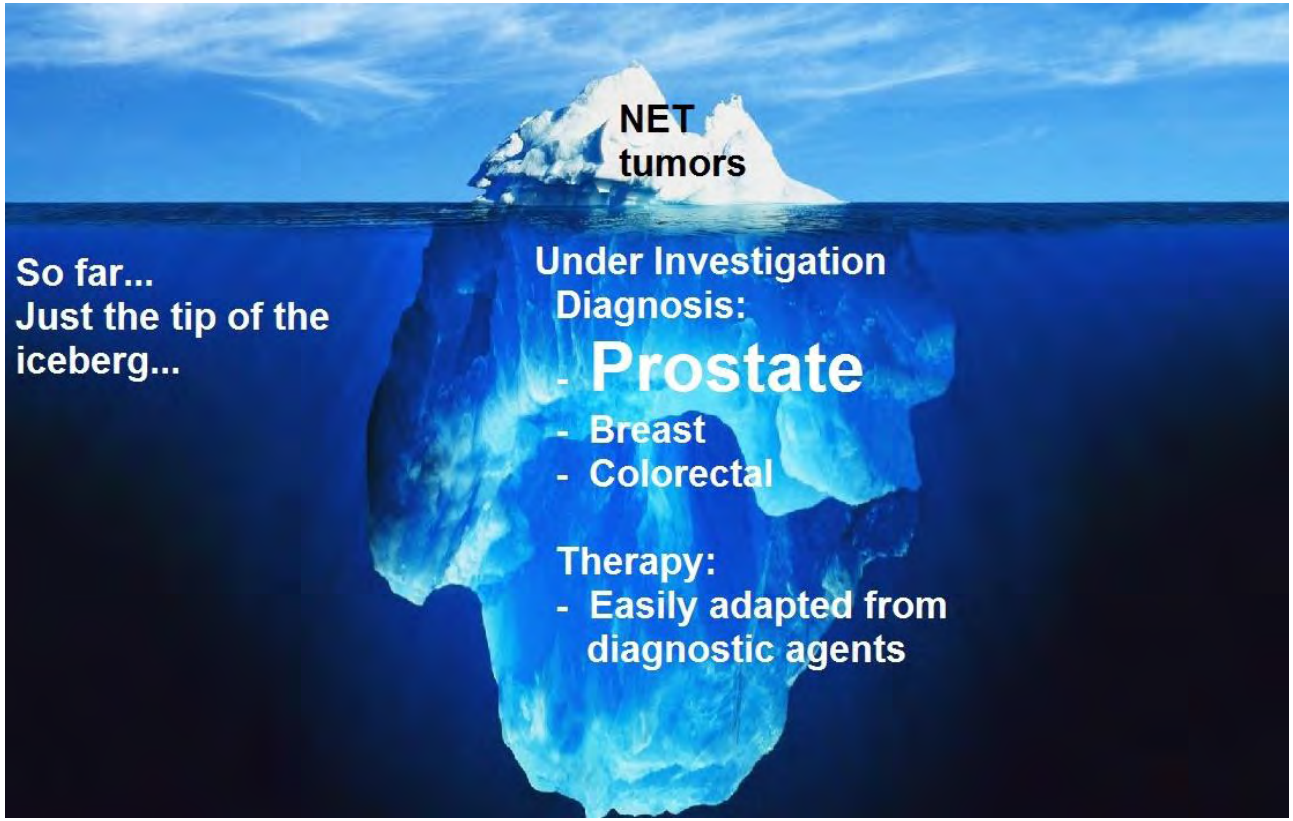
Ga-68 PET Radiopharmaceuticals

^{111}In-DTPA-Octreotide

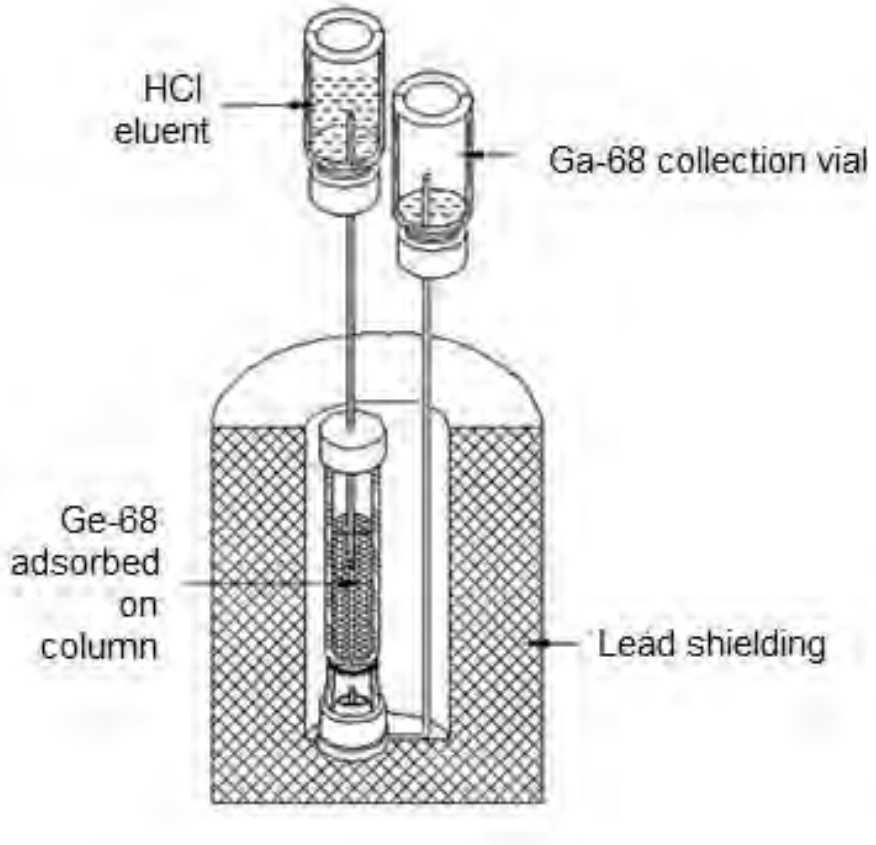


^{68}Ga-DOTA-TOC

Ga-68; now and in the near future



Ga-68 Generator



Decommissioning Funding Plan (DFP)

- **Triggered by the derived default value for unlisted radionuclides in Appendix B of Part 30. Ge-68's trigger level = 10 mCi.**
- **DFP is "extensive and expensive."**

-John Keklak, MS, CHP, RSO Thomas Jefferson University and Hospitals

Decommissioning Funding Plan (DFP)

- **“Every patient in need would not have equal access to these radiopharmaceuticals, most especially those in smaller and/or more rural markets.”**

  -Fred Gattas, PharmD, FAPhA, BCNP, Director of Quality and Safety for Triad Isotopes

ACMUI's Proposed Relief

- **The cost of decommissioning a medical use Ga-68 generator does not warrant the need for a DFP.**
- **The current DFP requirements have already and will continue to limit patient access to Ga-68's use.**

ACMUI's Proposed Relief

The Committee recommends the following language be added as a footnote to Appendix B Part 30 – Quantities of Licensed Material Requiring Labeling:

[3]This does not include Ge-68 in a Ge-68/Ga-68 medical use generators (limit less than 10 µci x 10^5) that are returned to the manufacturer at end of use.

NRC's Responsibility to Patients

Acronyms

- **ACMUI – Advisory Committee on the Medical Uses of Isotopes**
- **DFP – Decommissioning Funding Plan**
- **Ga-68 – Gallium-68**
- **Ge-68 – Germanium-68**
- **NET – Neuroendocrine Tumor**